

Attorney Docket: 052775-0311431

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE PATENT : David SCHMIDT
APPLICATION OF :
SERIAL NO. : 10/669,596
FILING DATE : September 25, 2003
ART UNIT : 1611
EXAMINER : ISIS A. D. GHALI
FOR : BIOMOLECULAR WEARABLE DEVICE

APPEAL BRIEF UNDER 37 C.F.R. § 41.37

Mail Stop APPEAL BRIEF - Patents

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the Office Action mailed **August 19, 2008** (the "Office Action"), and further to the Notice of Appeal and Request for Pre-Appeal Brief Request for Review filed October 7, 2008, Appellants respectfully submit an Appeal Brief pursuant to 37 C.F.R. § 41.37.

The Director is authorized to charge the \$500.00 fee for filing an Appeal Brief pursuant to 37 C.F.R. § 41.20(b)(2). The Director is further authorized to charge any additional fees that may be due, or credit any overpayment of same to Deposit Account No. 033975 (**Ref. No. 052775-0311431**).

REQUIREMENTS OF 37 C.F.R. §41.37

I. 37 C.F.R. § 41.37(c)(1)(i) – REAL PARTY IN INTEREST

The real party in interest is LifeWave Products, LLC.

II. 37 C.F.R. § 41.37(c)(1)(ii) – RELATED APPEALS AND INTERFERENCES

There are no related appeals and/or interferences.

III. 37 C.F.R. § 41.37(c)(1)(iii) – STATUS OF CLAIMS

Pending: Claims 1, 3, 5, 6, 10, 11, 14, 16, 18, 20, 22, 24, 26, 34, 36, 38, 42, 58, and 59 are pending.

Cancelled: Claims 2, 4, 7-9, 12, 13, 15, 17, 19, 21, 23, 35, 27-33, 35, 37, 39-41, and 43-57 have been cancelled without prejudice or disclaimer.

Rejected: Claims 1, 3, 5, 6, 10, 11, 14, 16, 18, 20, 22, 24, 26, 34, 38, 42, 58, and 59 stand rejected.

Withdrawn: Claim 36 has been withdrawn from examination.

Allowed: No claims have been allowed.

On Appeal: The rejection of claims 1, 3, 5, 6, 10, 11, 14, 16, 18, 20, 22, 24, 26, 34, 38, 42, 58, and 59 is appealed.

IV. 37 C.F.R. § 41.37(c)(1)(iv) – STATUS OF AMENDMENTS

No amendments have been entered subsequent to the mailing of the Office Action on August 19, 2008.

V. 37 C.F.R. § 41.37(c)(1)(v) – SUMMARY OF CLAIMED SUBJECT MATTER

A. INDEPENDENT CLAIMS

The claimed invention relates generally to a biomolecular wearable apparatus configured to regulate thermomagnetic energy flow within the human body for producing beneficial effects, such as an improvement in stamina and/or relief from pain [see, e.g., ¶ 2]. The apparatus operates non-invasively [see, e.g., ¶¶ 29 and 30]. In particular, in one embodiment, the apparatus holds one or more organic substances near the subject but external to the subject's body [see *id.*]. While the one or more organic substances are held close to the subject, they do not directly contact the subject, and the substances themselves do not enter the body [see, e.g., ¶¶ 29,30, and 35]. As such, the apparatus is non-transdermal [see *id.*].

1. Claim 1

In one embodiment, the invention relates to an apparatus [e.g., element 100 in FIGS. 2-7] for application to a subject's body to provide a beneficial biological effect for the subject [see, e.g., ¶ 2]. The apparatus may comprise at least one organic material, at least one substrate [element(s) 110 and/or 120 in FIGS. 2 and 3], and at least one enclosure. The at least one organic material may include a Left-Handed molecule [see, e.g., ¶ 32]. The at least one substrate may be for said at least one organic material [see, e.g., ¶¶ 30, 32, 36, and 70]. The at least one enclosure may be for enclosing said at least one organic material and said at least one substrate [see, e.g., ¶¶ 29 and 30]. The at least one enclosure may comprise an adhesive for adhering said at least one enclosure to said subject's body [see, e.g., ¶¶ 87, 94, and 106]. The at least one enclosure may prevent said at least one organic material from direct contact with said subject's body while said at least one enclosure is adhered to said subject's body using said adhesive [see, e.g., ¶¶ 29, 30, 35, and 80].

2. Claim 58

In one embodiment, the invention relates to an apparatus [e.g., element 100 in FIGS. 2-7] for application to a subject's body to provide a beneficial biological effect for the subject [see, e.g., ¶ 2]. The apparatus may comprise at least one organic material, at least one substrate [element(s) 110 and/or 120 in FIGS. 2 and 3], and at least one enclosure. The at least one organic material may include a Left-Handed molecule [see, e.g., ¶ 32]. The at least one substrate may be for said at least one organic material [see, e.g., ¶¶ 30, 32, 36, and 70]. The at least one enclosure may be for enclosing said at least one organic material and said at least one substrate [see, e.g., ¶¶ 29 and 30]. The at least one enclosure may prevent said at least one organic material from direct contact with said subject's body [see, e.g., ¶¶ 29, 30, 35, and 80]. The beneficial biological effect for the subject may accomplished by the apparatus while said at least one organic material and said substrate are enclosed in said at least one enclosure [see *id.*].

3. Claim 59

In one embodiment, the invention relates to an apparatus [e.g., element 100 in FIGS. 2-7] for application to a subject's body to provide a beneficial biological effect for the subject [see, e.g., ¶ 2]. The apparatus may comprise at least one organic material, at least one substrate [element(s) 110 and/or 120 in FIGS. 2 and 3], and at least one wearable object. The at least one organic material may include a Left-Handed molecule [see, e.g., ¶ 32]. The at least one substrate may be for said at least one organic material [see, e.g., ¶¶ 30, 32, 36, and 70]. The at least one wearable object may include at least one enclosure for enclosing said at least one organic material and said at least one substrate [see, e.g., ¶¶ 29 and 30]. The at least one enclosure may prevent said at least one organic material from direct contact with said subject's body while said at least one wearable object is worn on said subject's body [see, e.g., ¶¶ 29, 30, 35, and 80].

VI. 37 C.F.R. § 41.37(c)(1)(vi) – GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL.

Claims 1, 3, 5, 6, 10, 11, 14, 16, 18, 20, 22, 24, 38, 42, 58, and 59 currently stand rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 6,475,514 to Blitzer *et al.* (“Blitzer”); claim 26 currently stands rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Blitzer in view of U.S. Patent No. 6,558,695 to Moo-Young *et al.* (“Moo-Young”); and claim 34 currently stands rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Blitzer in view of U.S. Patent No. 6,558,695 to Luo *et al.* (“Luo”). These rejections constitute legal error, and should be reversed upon review.

VII. 37 C.F.R. § 41.37(c)(1)(vii) – ARGUMENT

Simply put, the invention relates to a wearable device having an organic material. The device contains the organic material within an enclosure such that the organic material is prevented from contacting a subject’s body, ***even during use*** (e.g., the device is non-transdermal). In stark contrast, the primary reference relied on by the Examiner (Blitzer) is indisputably a transdermal patch that delivers an organic material into the body of a user through the skin. For at least this reason the rejections must be reversed.

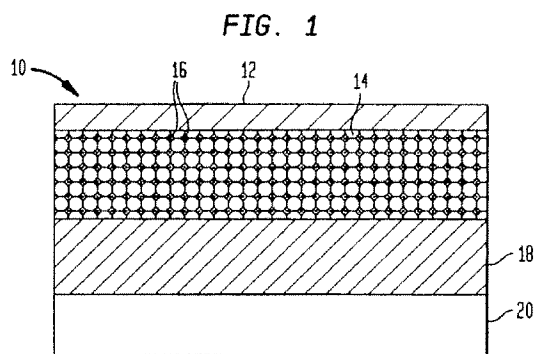
A. CLAIM 1 (and its dependent claims)

The rejection of claims 1, 3, 5, 6, 10, 11, 14, 16, 18, 20, 22, 24, 38, and 42 constitutes clear legal error at least because the Examiner has failed to demonstrate that Blitzer discloses all of the features of the claimed invention. In fact, the Examiner affirmatively acknowledges features of Blitzer that contrast with the recited features of the claimed invention, thus teaching away therefrom. For example, claim 1 recites the following features, which are not disclosed in the sections of Blitzer relied on by the Examiner:

...at least one enclosure for enclosing said at least one organic

material and said at least one substrate, wherein said at least one enclosure comprises an adhesive for adhering said at least one enclosure to said subject's body and wherein said at least one enclosure **prevents said at least one organic material from direct contact with said subject's body while said at least one enclosure is adhered to said subject's body using said adhesive.**

Generally, Blitzer discloses a transdermal patch that delivers nutrients into the blood stream of the body through the epidermis. See, e.g., Blitzer, c. 2, ll. 25-34. Blitzer discloses a specific embodiment, shown in FIG. 1 (reproduced below) in which an athletic supplement is carried in a polymer matrix 16. See, e.g., Blitzer, c. 18, ll. 26-36. The polymer matrix 16 is bounded on one side by a backing layer 12, and on the other side by a pressure sensitive adhesive layer 18 and a release liner 20. See, e.g., Blitzer, c. 17, l. 66-c. 18, l. 26. In use, liner 20 is removed or dissolved to expose adhesive 18, which secures the polymer matrix 16 to the skin of the user. See, e.g., Blitzer, c. 18, l. 65-c. 19, l. 6. Adhesive 18 and polymer matrix 16 are configured such that upon application of the patch to the skin of the user, the athletic supplement carried in polymer matrix 16 is released into the skin. See, e.g., Blitzer c. 9, ll. 64 and 65.



In rejecting claim 1, the Examiner alleges that the athletic supplement disclosed in Blitzer *can be interpreted* as the “at least one organic material” of claim 1, and that polymer matrix 16 and the adhesive 18 *can be interpreted* as the “at least one enclosure of claim 1.” The Office Action, p. 5. Without agreeing with the propriety of these interpretations, Blitzer expressly discloses that when the adhesive holds the patch in place on a user, the athletic supplement contained within the patch is released into the skin of the user. See, e.g., Blitzer c. 9, ll. 64 and 65. In fact, the Examiner has

acknowledged that the patch disclosed in Blitzer is a “transdermal patch for administration of [sic] nutrient supplement to a subject.” The Office Action, p. 3 (emphasis added). As such, the disclosure of Blitzer and the express admissions of the Examiner both indicate that athletic supplement is released from polymer matrix 16 into the skin of the user. The athletic supplement thus makes “direct contact” with the skin of the user and passes through it. Therefore, the polymer matrix and adhesive of the patch described in Blitzer do not “**prevent[] said at least one organic material from direct contact with said subject’s body while said at least one enclosure is adhered to said subject’s body using said adhesive.**” For at least this reason the rejection of claim 1 based on the cited sections of Blitzer constitutes a clear legal error and must be overturned.

Claims 3, 5, 6, 10, 11, 14, 16, 18, 20, 22, 24, 38, and 42 depend from claim 1. As such, the rejection of claims 3, 5, 6, 10, 11, 14, 16, 18, 20, 22, 24, 38, and 42 based on the cited sections of Blitzer constitute clear legal error and must be overturned due to the dependency of claims 3, 5, 6, 10, 11, 14, 16, 18, 20, 22, 24, 38, and 42, as well as for the features that they recite individually.

Claim 26 depends from claim 1. The sections of Moo-Young cited by the Examiner in rejecting claim 26 do not address the deficiencies of Blitzer with respect to claim 1 set forth above. Therefore, the rejection of claim 26 must be overturned due to its dependency, as well as for the features that it recites individually.

Claim 34 depends from claim 1. The sections of Lue cited by the Examiner in rejecting claim 34 do not address the deficiencies of Blitzer with respect to claim 1 set forth above. Therefore, the rejection of claim 34 must be overturned due to its dependency, as well as for the features that it recites individually.

B. CLAIM 58

The rejection of claim 58 constitutes clear legal error at least because the Examiner has failed to demonstrate that Blitzer discloses each and every feature of the claimed invention. For example, claim 58 recites *inter alia* the following features, which are not disclosed in the sections of Blitzer relied on by the Examiner:

...at least one enclosure for enclosing said at least one organic material and said at least one substrate, wherein said at least one enclosure prevents said at least one organic material from direct contact with said subject's body and **wherein the beneficial biological effect for the subject is accomplished while said at least one organic material and said substrate are enclosed in said at least one enclosure.**

By the Examiner's admission, Blitzer discloses a transdermal patch that releases an athletic supplement into the bloodstream of a user through the user's skin. The Office Action, pp. 3 and 5. Blitzer alleges that the athletic supplement provides a beneficial biological effect, but is clear in disclosing that the athletic supplement does not provide the intended effect unless it is released into the bloodstream through the skin. See, e.g., Blitzer, c. 2, ll. 25-34. Therefore, the "beneficial biological effect" of the athletic supplement of Blitzer is **not** "accomplished while [the athletic supplement is] enclosed in said at least one enclosure." For at least this reason the rejection of claim 58 constitutes clear legal error and must be overturned.

C. **CLAIM 59**

The rejection of claim 59 constitutes clear legal error at least because the Examiner has failed to demonstrate that Blitzer discloses each and every feature of the claimed invention. For example, claim 59 recites *inter alia* the following features, which are not disclosed in the sections of Blitzer relied on by the Examiner:

...at least one wearable object comprising at least one enclosure for said at least one organic material and said at least one substrate, wherein said at least one enclosure **prevents said at least one organic material from direct contact with said subject's body while said at least one wearable object is worn on said subject's body.**

As was demonstrated above with respect to claim 1, when the patch of Blitzer is adhered to the body of a user, the patch releases an athletic supplement into the body of the user through the user's skin. This is acknowledged by the Examiner (see the Office Action, p. 3), and is expressly stated in the disclosure of Blitzer (see c. 9, ll. 64 and 65). As such, the patch disclosed in Blitzer does not "**prevent[] said at least one organic material from direct contact with said subject's body while said at least**

one wearable object is worn on said subject's body." For at least this reason the rejection of claim 59 constitutes clear legal error and must be overturned.

VIII. 37 C.F.R. §41.37(c)(1)(viii) - CLAIMS APPENDIX

Appendix A: The pending claims are attached in Appendix A.

IX. 37 C.F.R. §41.37(c)(1)(ix) - EVIDENCE APPENDIX

Appendix B: (None)

X. 37 C.F.R. §41.37(c)(1)(x) - RELATED PROCEEDINGS INDEX

Appendix C: (None)

CONCLUSION

For at least the foregoing reasons, Appellant respectfully requests that the rejection of each of claims 1, 3, 5, 6, 10, 11, 14, 16, 18, 20, 22, 24, 26, 34, 38, 42, 58, and 59 be reversed.

Date: January 12, 2009

Respectfully submitted,

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APPENDIX A

CLAIMS

1. (***Previously Presented***) An apparatus for application to a subject's body to provide a beneficial biological effect for the subject, the apparatus comprising:
at least one organic material including a Left-Handed molecule;
at least one substrate for said at least one organic material; and
at least one enclosure for enclosing said at least one organic material and said at least one substrate, wherein said at least one enclosure comprises an adhesive for adhering said at least one enclosure to said subject's body and wherein said at least one enclosure prevents said at least one organic material from direct contact with said subject's body while said at least one enclosure is adhered to said subject's body using said adhesive.

2. (***Canceled***)

3. (***Original***) The apparatus of claim 1, comprising a plurality of Left-Handed molecules.

4. (***Canceled***)

5. (***Original***) The apparatus of claim 1, wherein said Left-Handed molecule is capable of causing the beneficial biological effect by interacting with a thermomagnetic energy-flow within the human body.

6. (***Original***) The apparatus of claim 1, wherein said Left-Handed molecule is an amino acid, wherein said amino acid is selected from a group consisting of L-Alanine, L-Arginine, L-Asparagine, L-Aspartic Acid, L-Carnitine, Acetyl-L-Carnitine, L-Carnitine L-Tartrate, L-Carnitine Magnesium Citrate, L-Citrulline, L-Cysteine, L-Cystine, L-GABA, L-Glutamic Acid, L-Glutamine, Glutathione Peroxidase, L-Glycine, L-Histidine, Hydroxyglutamic Acid, Hydroxyproline, L-Isoleucine, L-Leucine, Norleucine, L-Lysine, L-

Methionine, L-Omithine, L-Valine, L-Phenylalanine, L-Proline, L-Serine, L-Taurine, L-Threonine, L-Tryptophan, and L-Tyrosine.

7-9. (**Canceled**)

10. (**Original**) The apparatus of claim 1, wherein the Left-Handed molecule is an amino acid, wherein said amino acid is selected from a group consisting of L-Arginine, L-Camitine, Acetyl-L-Carnitine, L-Carnitine L-Tartrate, L-Carnitine Magnesium Citrate, L-Glutamine, L-Methionine, L-Ornithine, and L-Taurine.

11. (**Original**) The apparatus of claim 1, wherein the Left-Handed molecule is an amino acid, wherein said amino acid is selected from a group consisting of L-Carnitine, Acetyl-L-Carnitine, L-Camitine L-Tartrate, and L-Carnitine Magnesium Citrate.

12-13. (**Canceled**)

14. (**Original**) The apparatus of claim 1, wherein said at least one substrate is polyester or cotton.

15. (**Canceled**)

16. (**Original**) The apparatus of claim 1, wherein said at least one enclosure is made of a plastic film, wherein the plastic film is selected from a group consisting of polyethylene, polypropylene, ABS, plexiglass, lexan, light polarizing film, and linear low density film.

17. (**Canceled**)

18. (**Original**) The apparatus of claim 1, wherein said at least one enclosure is made of at least one of a light polarizing film and a linear low density film.

19. (**Canceled**)

20. (**Original**) The apparatus of claim 1, further comprising one or more adhesive portions so as to attach said apparatus on a skin surface of the subject.

21. (**Canceled**)

22. (**Original**) The apparatus of claim 20, wherein said one or more adhesive portions includes a medical grade adhesive.

23. (**Canceled**)

24. (**Original**) The apparatus of claim 20, wherein said apparatus can be placed in a predetermined location of a human body.

25. (**Canceled**)

26. (**Original**) The apparatus of claim 1, wherein said apparatus is embodied in a bracelet.

27-33. (**Canceled**)

34. (**Original**) The apparatus of claim 1, wherein the apparatus further comprising one or more additives for said at least one organic material, wherein said one or more additives are selected from a group consisting of Glycerin, d-calcium pantothenate, sorbitol, propylparaben, potassium sorbate, methylparaben, and Colloidal Gold.

35. (**Canceled**)

36. (**Withdrawn**) The apparatus of claim 1, further comprising one or more patches, wherein said patch(s) is (are) constructed in layers, said layers including a plastic film or a light polarizing film as an enclosure, a polyester fabric as a substrate, Water, L-Carnitine, Glycerin, d-calcium pantothenate, sorbitol, propylparaben, potassium sorbate, and methylparaben.

37. (**Canceled**)

38. (**Original**) The apparatus of claim 1, further comprising one or more patches, wherein said patch(s) is (are) constructed in layers, said layers including a plastic film or a light polarizing film as an enclosure, a polyester fabric as a substrate, honey, and molasses.

39-41. (**Canceled**)

42. (**Original**) The apparatus of claim 1, wherein the beneficial biological effect is an improvement in the subject's stamina.

43-57. (**Canceled**)

58. (***Previously Presented***) An apparatus for application to a subject's body to provide a beneficial biological effect for the subject, the apparatus comprising:

- at least one organic material including a Left-Handed molecule;
- at least one substrate for said at least one organic material; and
- at least one enclosure for enclosing said at least one organic material and said at least one substrate, wherein said at least one enclosure prevents said at least one organic material from direct contact with said subject's body and wherein the beneficial biological effect for the subject is accomplished while said at least one organic material and said substrate are enclosed in said at least one enclosure.

59. (***Previously Presented***) An apparatus for application to a subject's body to provide a beneficial biological effect for the subject, the apparatus comprising:

- at least one organic material including a Left-Handed molecule;
- at least one substrate for said at least one organic material; and
- at least one wearable object comprising at least one enclosure for said at least one organic material and said at least one substrate, wherein said at least one enclosure prevents said at least one organic material from direct contact with said subject's body while said at least one wearable object is worn on said subject's body.

APPENDIX B

EVIDENCE APPENDIX

NONE

APPENDIX C

RELATED PROCEEDINGS INDEX

NONE